

## **REMARKS**

### ***Claim Amendments***

Claims 1-65 are cancelled without prejudice or disclaimer. New claims 66-81 are added. Applicant reserves the right to pursue the subject matter of the cancelled claims in one or more divisional or continuation application(s). Support for the claim amendments and new claims can be found throughout the specification, for example at ¶¶ [032], [181]-[192], [287]-[295], [378], Examples 3-6, and in the claims as originally filed. Applicant respectfully requests entry of this amendment and submits that the new claims do not constitute new matter.

### ***Specification Amendments***

Applicant has amended the specification to include Table numbers and to capitalize the trademarks FACScalibur and CellQuest. Support for the amendments can be found throughout the specification. Applicant respectfully requests entry of the above amendment and submits that the above amendment does not constitute new matter.

### ***Interview Summary Pursuant to 37 C.F.R. § 1.133(b)***

In accordance with 37 C.F.R. § 1.133(b) and M.P.E.P. § 713.04, Applicant provides herein a summary of the interview held on June 19, 2007, with Primary Examiner Saoud and Examiner Seharaseyon and Applicant's representatives. Applicant thanks Examiners Saoud and Seharaseyon for agreeing to conduct the interview and appreciate the courtesies extended by the Examiners.

During the interview, the Examiners and Applicant's representatives discussed cancelling the previously pending claims and adding new claims drawn to SEQ ID NO: 2 comprising a SNP, sequences with at least 95% sequence homology comprising a SNP coupled with functional language, and compositions comprising the same. The parties also discussed these proposed claims in light of the enablement and written description rejections of record.

### ***Objection to the Specification***

The specification was objected to because of informalities. Applicant has amended the specification rendering this objection *moot*.

### ***Claim Objections***

Claims 27, 28, 37, 42, 47, 48, and 51-65 stand objected to because, according to the Office Action, it was not clear if amino acid position 45 was relative to the start of the full-length SEQ ID NO: 2 or relative to the start of the polypeptide at amino acid 24 of SEQ ID NO: 2. Applicant has cancelled claims 27, 28, 37, 42, 47, 48, and 51-65 rendering this objection *moot*.

### ***Written Description Rejection under 35 U.S.C. § 112, first paragraph***

Claims 27, 28, 42, 48, 51-58, 60, 61, 64, and 65 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicant traverses this rejection.

Without acquiescing to the correctness of the rejection, Applicant has cancelled claims 27, 28, 42, 48, 51-58, 60, 61, 64, and 65 rendering this rejection *moot*. Applicant, however, provides the following remarks.

Initially, Applicant submits that polypeptides belonging to the IFN $\alpha$  family share a common structure and common antiviral, antiproliferative, or immunomodulatory activities. See e.g., specification at ¶¶ [007]-[012]. Applicant further submits that the specification describes polypeptide comprising an amino acid sequence having at least 95% identity with the amino acid sequence SEQ ID NO. 2, or the amino acid sequence comprising amino acids 24 and 189 of the amino acid sequence SEQ ID NO. 2 and contain the G45R SNP. See e.g., ¶¶ [181]-[192]. The specification also describes that wild-type IFN $\alpha$ -17 gene codes for an immature protein of 189 amino acids (e.g., SEQ ID NO. 2) that can be converted to a mature protein of 166 amino acids by cleavage of the signal peptide that includes the first 23 amino acids (e.g., amino acids 24 to 189 of SEQ ID NO. 2). See e.g., ¶ [032]. Furthermore, the specification provides a description of IFN $\alpha$ -17 polypeptides with antiviral, antiproliferative, or immunomodulatory activity. See e.g., Examples 3-6. Accordingly, Applicant submits that the specification reasonably conveys to one of skill in the art that Applicant had possession of the claimed invention at the time the application was filed.

***Enablement Rejection under 35 U.S.C. § 112, first paragraph***

Claims 27, 28, 42, 48, 51-58, 60, 61, 64, and 65 stand rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the Office Action. Applicant traverses this rejection.

Without acquiescing to the correctness of the rejection, Applicant has cancelled claims 27, 28, 42, 48, 51-58, 60, 61, 64, and 65 rendering this rejection *moot*. Applicant, however, provides the following remarks.

Initially, Applicant submits that polypeptides belonging to the IFN $\alpha$  family share a common structure and common antiviral, antiproliferative, or immunomodulatory activities. See e.g., specification at ¶¶ [007]-[013]. Applicant further submits that the specification teaches polypeptides comprising an amino acid sequence having at least 95% identity with the amino acid sequence SEQ ID NO. 2, or the amino acid sequence comprising amino acids 24 and 189 of the amino acid sequence SEQ ID NO. 2 and contain the G45R SNP. See e.g., specification at ¶¶ [181]-[192]. The specification also teaches that wild-type IFN $\alpha$ -17 gene codes for an immature protein of 189 amino acids (e.g., SEQ ID NO. 2) that can be converted to a mature protein of 166 amino acids by cleavage of the signal peptide that includes the first 23 amino acids (e.g., amino acids 24 to 189 of SEQ ID NO. 2). See e.g., specification at ¶ [032]. Furthermore, the specification teaches several assays for identifying polypeptides with antiviral, antiproliferative, or immunomodulatory activity. See e.g., specification at Examples 3-6. Accordingly, Applicant submits that the specification provides the requisite guidance to teach one of skill in the art how to make and use the claimed polypeptides and compositions without undue experimentation.

***Enablement Rejection under 35 U.S.C. § 112, first paragraph***

Claims 37, 64, and 65 stand rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the Office Action. Applicant traverses this rejection.

Without acquiescing to the correctness of the rejection, Applicant has cancelled claims 37, 64, and 65 rendering this rejection *moot*. Applicant, however, provides the following remarks.

IFN $\alpha$  is used for treatment of various viral diseases and cancers. See e.g., ¶¶ [012]-[013]. The specification teaches that polypeptides of the invention also demonstrate antiviral and antitumoral (antiproliferative) activity. See e.g., Examples 4-6. Indeed, Example 6(a) shows

that G45R mutated IFN $\alpha$ -17 has an antiviral activity higher than that of wild-type IFN $\alpha$ -2. See e.g., ¶¶ [428]-[432]. Further, Example 5 shows that G45R mutated IFN $\alpha$ -17 has an antitumoral (antiproliferative) activity higher than that of wild-type IFN $\alpha$ -2. See e.g., ¶¶ [415]-[419]. In view of these results, it is clear to the skilled artisan that the polypeptides of the invention can be used to treat the same disorders and diseases as wild-type IFN $\alpha$  and, in particular, the same viral diseases and cancers.

**CONCLUSION**

Applicant respectfully submits that claims are in condition for allowance, and such disposition is earnestly solicited. Should the Examiner believe that any issues remain after consideration of this response, the Examiner encouraged to contact the Applicant's undersigned representative to discuss and resolve such issues.


In the event that a variance exists between the amount tendered and that deemed necessary by the U.S. Patent and Trademark Office to enter and consider this response or to maintain the present application pending, please credit or charge such variance to the undersigned's **Deposit Account No. 50-0206**.

Respectfully submitted,

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